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10/092,285	03/05/2002	John Hinchcliffe	9301-171-999	7757

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,285	HINCHCLIFFE, JOHN	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/18/06, 4/28/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29,32,33,69 and 71-99* is/are pending in the application.

4a) Of the above claim(s) *71-99* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29,32,33,69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of species 1) in the reply filed on August 18, 2006 is acknowledged. The traversal is on the ground(s) that, contrary to Examiner's assertion, both species could easily and within the scope of the claims, have the same type of access to the interior of the cartridge, for example, the holes (52) and (54) in figure 1. This is not found persuasive because the cover would not be completely sealed. This is also supported by Applicant's argument in the response filed April 28, 2006, (page 14, second full paragraph) that a cover with an opening is not completely sealed.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-6, 12, 17-22 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton, 3,582,285, in view of Schembri et al., 6,258, 593.

Hamilton discloses the invention substantially as claimed. More specifically, Hamilton discloses a microarray cartridge comprising :

a body (i.e., container 10) having a wall (30) forming a cavity (i.e., reaction compartment 14) surrounded by a mating surface (i.e., flange 24), the body comprising a reaction chamber (i.e., reaction compartment 14) and at least one microarray support contained within the cavity (i.e., flat portion 40); and

a cover (i.e., membrane 26) that is covering the cavity and is sealingly adhered with the mating surface of said body by non-removable adhering means (i.e., heat-sealed, see col. 9, lines 25-26). It is noted that Applicant is invoking 112, 6th paragraph, and that heat sealing is disclosed in Applicant's specification on page 3, lines 26-28 and page 7, line 25). The cover is considered to be sealingly adhered by non-removable adhering means on all but one edge of the mating surface, said all but one edge being unsealed to said cover, because the cover (26) is disclosed as being peeled by the user during use (col. 9, lines 33-36). Thus, at a particular time during use when the cover is partially opened, the cover is sealingly adhered on all but one edge of the mating surface, said all but one edge being unsealed to the cover.

While Hamilton teaches that the device is a test package for the mixing and reaction of reagents and sample material (col. 1, lines 11-13), Hamilton however does not teach that the microarray support supports a microarray slide within the cavity such that a surface of the slide covers the reaction chamber, and that the slide is disposed between the cover and the reaction chamber.

Schembri et al. however teach these limitations by teaching an apparatus for conducting chemical or biochemical reactions on a solid surface, as in hybridization assays in which surface-bound molecular probes selectively bind target molecules in a solution (col. 1, lines 8-12). Schembri et al. teach that the apparatus includes a base (2) with a reaction chamber for receiving a substrate (2), upon which a cover may be fitted, (see fig. 1). Schembri et al. teach that the substrate surface has a plurality of molecular probes bound thereto and serves as a hybridization region, and preferably the molecular probes are arranged in a spatially defined and physically addressable matter, i.e., in an array (col. 9, lines 16-22). Schembri et al. disclose that the location of the signals in the array allows for target identification (col. 1, lines 57-58, and col. 2, lines 9-24). (It is noted that the "array" disclosed by Schembri et al. is considered to be a microarray because the dimension is relatively small—see the disclosed dimensions of the reaction area in col. 9, lines 10-15). t would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a substrate having an array of molecular probes as taught by Schembri et al. in the Hamilton reaction chamber because Schembri et al. teach that a substrate having an array of molecular probes provides the benefit of allowing for target identification. (It is noted that the Schembri et al. substrate (2) is a slide (see fig. 1).

As to the following claims, Hamilton discloses the limitations as follows.

As to claim 2, the non-removable adhering means comprises a heat seal between said cover and the mating surface of said body (col. 9, lines 25-26).

As to claim 4, the non-removable adhering means does not include a mechanical fastener (col. 9, lines 25-26).

As to claim 5, the cartridge further comprises a plurality of microarray supports (i.e., different portions of flat portion 40) within the cavity for positioning the microarray slide. It is noted that Applicant has not claimed the specific structures of the microarry supports such that they are distinguished over the prior art reference.

As to claim 6, the cartridge further comprises a first access site (i.e., the opening to the reaction compartment 14) communicating with the reaction chamber for passing fluids from a delivery device and into the reaction chamber. It is noted that Applicant has not claimed the specific structure or location of the first access site such that it is distinguished over the prior art reference.

As to claim 24, Hamilton teaches at least 4 cavities (16, 18, 20 and 22) with microarray supports (e.g., the side walls of the cavities). It is noted that Applicant does not recite that the at least 4 cavities each have a slide.

As to claims 12, 17-22 and 25-27, Hamilton does not teach that the thickness of the first access site is between 0.003 and 0.015 inches (claim 12), the thickness of the body wall is less than 0.065 inches (claim 17), or between 0.005 and 0.025 inches (claim 18), or between .010 and .015 inch (claim 19), or less than 0.1 inch (claim 20), or between 0.032 and 0.075 inch (claim 21), or between 0.040 and 0.060 inches (claim 22), nor that the reaction chamber has a volume of at least 500 uL (claim 25), or at least 1 mL (claim 26), or 1 mL to 3 mL (claim 27).

However, Schembri et al. teach that providing chambers having small dimensions are known in the art (see col. 9, lines 10-15, disclosing dimensions in the millimeter range and reaction chambers in the microliter range). Moreover, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, Hamilton disclose the general conditions of the claims and the dimensions of the body wall and the reaction chamber as claimed by Applicant are optimum or workable ranges and thus its discovery involves only routine skill in the art under *In re Aller.*

Claims 7-11, 13-16, 23, 28, 29, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton, 3,582,285, in view of Schembri et al., 6,258, 593, and further in view of Dvorak et al., 3,726,597.

Hamilton in view of Schembri et al. teach the invention substantially as claimed (see above), except for the first access site being located on said body, wherein the access site is dimensioned to pass fluids from a fluid delivery device through the body wall and into the reaction chamber (as recited in claim 7), or the body further comprising a first dimple feature in communication with the reaction chamber and the first access site, the first dimple feature forming a passage for a fluid around a first edge of the microarray slide and into the reaction chamber when the microarray slide is placed in the cavity (as recited in claim 8), or the first access site being located on said body and

communicates with said dimple feature, such that fluid from the fluid delivery device passes through the body wall and into the dimple feature, (as recited in claim 9).

However, Dvorak et al. teach an apparatus having a chamber wherein the wall of the chamber has openings serving as a perfusion ports with tubing (20), (col. 3, lines 39-40). Dvorak et al. also teach that the apparatus allows for continuous perfusion of the chamber (col. 6, lines 1-2). While Dvorak et al. teach that the chamber is cell or tissue chamber (col. 3, line 26), Dvorak et al. nevertheless teach that a wall structure of a chamber having openings for providing fluid into the chamber. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an opening in the wall of the Hamilton chamber as taught by Dvorak et al. because Dvorak et al. teach that such an opening provides the benefit of providing fluids to the chamber as well as providing continuous perfusion. One of ordinary skill in the art would recognize the benefits of such a perfusion port for various reactions.

It is noted that the perfusion port is considered to be Applicant's claimed access site dimensioned to pass fluids from a fluid delivery device through the body wall and into the reaction chamber as recited in claims 7 and 9, or the first dimple features as recited by Applicant in claim 8

As to claim 10, the perfusion port disclosed by Dvorak et al. is considered to be Applicant's claimed first dimple feature. Applicant also claims that the first access site is located on the cover and communicates with said dimple feature, such that fluid from the fluid delivery device passes through the cover and into the dimple feature. It would have been obvious to one of ordinary skill in the art at the time the invention was made

that in the modification of the Hamilton chamber such that the wall includes a perfusion port and tubing as taught by Dvorak et al., the Hamilton membrane must include an opening in order to permit access of the Dvorak et al. tubing in the perfusion port. Such an opening is considered to be the first access site located on the cover (i.e., membrane) as recited in claim 10. The Office also notes that this membrane around this opening and tubing can also be considered an unsealed edge as recited in claim 1.

As to claim 11, Applicant claims that the first access site is an open port and the fluid delivery device is a pipette dimensioned to deliver fluids through the port. The opening discussed above regarding claim 10 is considered to be the first access site. (Examiner notes that the pipette is not positively claimed as part of the claimed cartridge. The first access site is capable of receiving fluid from a pipette and thus meets this limitation.)

As to claim 13, Applicant claims that the body further comprises a second dimple feature in communication with the reaction chamber, the second dimple feature forming a passage for fluids around a second edge of the microarray slide and into the reaction chamber when the microarray slide is placed in the cavity. One of the other perfusion ports with tubing (20) disclosed by Dvorak et al. is considered to be the claimed second dimple feature forming a passage for fluids around a second edge of the microarray side.

As to claim 14, Applicant claims that the cartridge further includes a second access site communicating with the second dimple feature for passing fluids into or out

of the reaction chamber. The second access site is considered to be the top of the perfusion port disclosed by Dvorak et al.

As to claim 15, the first access site (i.e., the top of the perfusion port disclosed by Dvorak et al.) is an open end of the cartridge, said cartridge further comprising a flange feature (24, see fig. 1 in Dvorak et al. reference) at the open end to facilitate entry of a fluid delivery device through the first access site before sealingly cohering said cover to said body at the open end. As mentioned above, with the modification of the Hamilton invention, the Hamilton membrane around the perfusion port/tubing taught by Dvorak et al. is considered to be the unsealed edge.

As to claim 16, the flange feature (24) comprises a first flange (i.e., one portion of 24) attached to and extending from an edge of said body at the access site and a second flange (i.e., another portion of 24) attached to and extending from a corresponding edge of said cover, such that the first and second flanges facilitate passage of the fluid delivery device through the open end of the cartridge between the body and the cover. It is noted that the fluid delivery device is not claimed as part of Applicant's claimed invention and relates to intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the prior art structure is capable of performing the intended use.

As to claim 23, Applicant claims that the body includes a plurality of cavities, each of the plurality of cavities having a corresponding reaction chamber and at least one corresponding microarray support for supporting a microarray slide. Hamilton teaches a plurality of cavities (reaction compartments 12 and 14), and, as previously discussed, Schembri et al. teach the motivation to provide a slide inside a reaction chamber.

As to claim 28, the body further includes a plurality of obstacles (i.e., sides of the reaction compartment 14, or alternatively, the bottom surface of the membrane 26, disclosed by Hamilton) within the reaction chamber arranged to affect motion of fluid within the chamber. It is noted that the limitations regarding affecting motion of fluid relates to intended use, and the Hamilton reaction compartments are capable of performing this intended use.

As to claim 29, the obstacles (i.e., sides of the reaction compartment 14, or alternatively, the bottom surface of the membrane 26, disclosed by Hamilton) are attached to a surface of the reaction chamber opposite the microarray.

As to claims 32 and 33, Applicant claims that the microarray slide comprises an array of nucleic acid probes distributed on the surface of a glass substrate, and the microarray slide is positioned such that the probes are in communication with a fluid in the reaction chamber, and the fluid includes nucleic acid molecules under conditions conductive to hybridization. Dvorak et al. teach these limitations (see col. 9, lines 17-33; and col. 10, lines 62-63).

Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton, 3,582,285, in view of Schembri et al., 6,258, 593, and further in view of Hill, 5,417,576.

Hamilton in view of Schembri et al. teach the invention substantially as claimed (see above regarding claim 1), except for the cover being configured to hingably cover the cavity.

However, Hill discloses an apparatus having a cover and a base with a chamber for containing microbiological matter (col. 1, lines 9-14; and col. 5, lines 56-57). Hill teaches that the cover is attached to the base by a hinge (18) (col. 6, lines 25-27; and col. 8, lines 1-3). Hill additionally teaches that a gasket or some sort of sealant could be placed between the base and cover to create an airtight sealing of the chamber (col. 6, lines 41-44). Such sealant being adhesives (col. 8, lines 10-11; and col. 12, lines 1-3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a hinge as taught by Hill on the Hamilton cover because Hill teaches that a hinge provides the purpose of attaching the cover to the base that forms the reaction compartment and one of ordinary skill in the art would recognize the benefit of convenience in attaching a cover to a base. Also, it is noted that while the Hamilton cover is disclosed as a membrane, it may be made of various materials such as plastic or aluminum foil (col. 9, lines 58-63). Moreover, one of ordinary skill in the art would have reasonable expectation of success in combining the references because Hill teaches that a cover that is sealed, such as the Hamilton cover, can additionally have a

hinge (col. 6, lines 41-44 and col. 8, lines 10-11 and col. 12, lines 1-3). (Also, it is noted that the cover (i.e., Hamilton membrane) contiguously extends from an edge of the mating surface and sealingly adheres with the mating surface of said body, as claimed by Applicant.)

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton, 3,582,285, in view of Schembri et al., 6,258, 593, and further in view of Lipton, 5,770,441.

Hamilton in view of Schembri et al. teach the invention substantially as claimed (see above regarding claim 1), except for the non-removable means being a non-removable adhesive seal between the cover and the mating surface of the body.

However, Lipton teaches an apparatus having a member (2) with compartments (3), and a cover sheet (6) to keep the compartment free from moisture and free from contaminants which may be present in the outside environment (col.13, lines 26-29). Lipton teaches that the cover sheet may be attached by heat sealing or gluing (col. 14, lines 53-55). Lipton discloses that the cover can be adhesively secured to the top of the compartment (col. 13, lines 58-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an adhesive seal as taught by Lipton as a substitute for the heat seal taught by Hamilton (see col. 9, lines 25-26) because Lipton teaches that an adhesive seal provides the equivalent function of sealing a cover onto a base as a heat seal.

Response to Arguments

Applicant's arguments filed April 28, 2006 have been fully considered but they are not persuasive with respect to the rejections that have been maintained.

It is noted that new grounds of rejection are made above as necessitated by the amendments to the claims.

The arguments with respect to the arguments regarding Gabridge, Angros and Dudek are moot because the rejections under these references have been withdrawn.

With respect to the Lipton reference, Applicant argues that the cover of Lipton is not sealingly adhered by non-removable adhering means but rather the cover sheet of Lipton includes a pull tab to facilitate removal of the cover sheet. This argument is not persuasive because according to Applicant's specification, a non-removable adhering means include adhesives and Lipton discloses an adhesive. Applicant appears to be arguing that the cover of Applicant's invention is not removed during use, in contrast to the disclosure of Lipton that the cover sheet is removed. However, Applicant is claiming an apparatus, and it is noted that such an intended use is in any case not recited in the claims. Even if the intended use were to be recited in Applicant's claim, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant's argument that Lipton requires openings and thus is not completely sealed, in contrast to independent claim 71, is moot because claim 71 is withdrawn in view of the election.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

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